

EXHIBIT 1

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION
LIFE TECHNOLOGIES)(
CORPORATION, ET AL.,)(CIVIL DOCKET NO.
(2:09-CV-283-TJW-CE
VS.)(MARSHALL, TEXAS
(
BIOSEARCH TECHNOLOGIES,)(AUGUST 23, 2011
INC.)(9:00 A.M.
CLAIM CONSTRUCTION HEARING
BEFORE THE HONORABLE JUDGE CHAD EVERINGHAM
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

FOR THE PLAINTIFFS: (See Attorney Sign-In Sheet)

FOR THE DEFENDANTS: (See Attorney Sign-In Sheet)

COURT REPORTER: MS. SHELLY HOLMES, CSR
Deputy Official Court Reporter
2593 Myrtle Road
Diana, Texas 75640
(903) 663-5082

(Proceedings recorded by mechanical stenography,
transcript produced on a CAT system.)

Page 2

I N D E X

August 23, 2011

Page

Appearances 1
Hearing 3
Court Reporter's Certificate 70

Page 3

1 LAW CLERK: All rise.
2 THE COURT: Please be seated.
3 All right. Good morning.
4 MR. JOHNSON: Morning.
5 MR. MALONEY: Morning, Your Honor.
6 THE COURT: We have a Markman hearing in
7 Life Technologies against Biosearch and others. It's
8 Case 2:09-CV-283.
9 What says the Plaintiff?
10 MR. MALONEY: Your Honor, Colin Maloney,
11 here with Cora Schmid and Emanuel Vacchiano. We're here
12 ready to proceed, Your Honor, for the Plaintiff.
13 THE COURT: Good morning.
14 For the Defendant?
15 MR. HAWES: Morning, Your Honor. Erik
16 Hawes, Morgan, Lewis and Bockius. I'm here with Dan
17 Johnson and Rita Tautkus. We're ready to proceed, Your
18 Honor.
19 THE COURT: Good morning.
20 MR. JOHNSON: Good morning.
21 THE COURT: All right. I've set aside an
22 hour and a half per side for argument. I've looked at
23 the briefing and the tutorials. I'm fairly familiar
24 with the actual disputes.
25 So, Mr. Maloney, I think you know the rule

Page 4

1 on opening. You need to use at least half of your time
2 in your opening presentation, otherwise, you're limited
3 to a reduced amount of time for rebuttal.
4 MR. MALONEY: Thank you, Your Honor.
5 THE COURT: With that, you may proceed.
6 MR. MALONEY: Thank you. Ms. Schmid is
7 going to give our presentation, Your Honor.
8 THE COURT: All right. Ms. Schmid.
9 MS. SCHMID: Good morning, Your Honor.
10 THE COURT: Morning.
11 MS. SCHMID: I'm Cora Schmid from Life
12 Technologies here on behalf of Plaintiffs, Life
13 Technologies and Applied Biosystems.
14 As Your Honor saw in the briefing,
15 Plaintiffs are asserting five patents in this case,
16 which are a family of patents that we refer to as the
17 Livak patents for the primary inventor, Dr. Kenneth
18 Livak.
19 The first patent in this family is what we
20 call the '848 patent. As all of the other four patents
21 claim priority to the '848 patent, we'll be citing to
22 the specification of the '848 patent, and all the
23 citations to the specification of the '848 patent
24 include all five of the patents.
25 Likewise, the other four patents are all

Page 5

1 continuations-in-part of the '848 patent and share
2 essentially identical specifications. So citations to
3 the '591 patent, for simplicity, will be used to
4 reference the specifications of all four of those
5 patents.

6 We're going to be talking about three
7 categories of claim terms. The first three terms that
8 we're going to be discussing include clear definitions
9 of the terms in the specifications, and the Court should
10 adopt those definitions as the construction.

11 In the second category, terms four and five,
12 the claims do not require construction and Defendants
13 show this by using the very words of the claim term in
14 their proposed construction.

15 Finally, the last three terms, terms six,
16 seven, and eight, Defendants argue are
17 means-plus-function terms, however, these terms don't
18 use the word means, which creates a strong presumption
19 that they're not means-plus-function, and in addition,
20 all three of those disclose a clear structure,
21 oligonucleotide sequences or oligonucleotide probes, and
22 so are not means-plus-function. They're also not
23 indefinite and do not require construction.

24 We'll now go through each of these terms in
25 these categories. As I mentioned, the first category or

Page 6

1 the first three terms in which the patentee defined the
2 term in the specification. Quick review of the law,
3 Phillips has made clear that -- that a claim term is
4 generally given its plain and ordinary meaning or its
5 ordinary and customary meaning, however, the patentee
6 can act as their own lexicographer, and that is, they
7 can give a term a special definition as long as it's
8 clear in the specification, and when that happens, the
9 Court should use that definition as the claim
10 construction. Indeed, the specification has been
11 recognized as the single best guide to the meaning of a
12 disputed term.

13 Now, the first term that we're going to talk
14 about today is quencher molecule. The basic dispute
15 between the parties is whether or not quencher molecules
16 that emit light, that is, quencher molecules that are
17 called fluorescent are going to be excluded from the
18 word quencher molecule.

19 Now, if we look at the specification, the
20 specification is clear that the definition of quencher
21 molecule should be broader than that. Specifically, the
22 mol -- the definition is the term that Plaintiffs
23 propose, and it's def -- it is defined in terms of
24 absorbing fluorescent energy and quenching a florescent
25 signal. It's not defined in terms of what it does with

Page 7

1 that energy, that is, whether it fluoresces the energy
2 and emits it as light or whether it dissipates it in a
3 different way.

4 This -- while a patentee can act as their
5 own lexicographer and give a word a special definition,
6 in this case, all the patentees have done is made clear
7 what the plain and ordinary meaning of the word is,
8 which Defendants have recognized.

9 In the tutorial they submitted to this
10 Court, they showed two kinds of quenchers, a quencher
11 that is a fluorescent quencher, which absorbs the light
12 from a reporter molecule over here and emits it as
13 lights or fluorescence, and quenchers that they call
14 dark quenchers, which absorb the light from a reporter
15 but do not emit it as light.

16 And as you can see right there, they even
17 specifically call this type of molecule a quencher under
18 it's plain and ordinary meaning, just a dark quencher
19 instead of a fluorescent quencher.

20 Now, the intrinsic evidence is just riddled
21 with examples that quencher molecule is broad enough to
22 include both fluorescent and nonfluorescent quencher
23 molecules. If you look at the words of the claims
24 themselves, you can see that sometimes the patentee
25 describes a quencher molecule and sometimes they

Page 8

1 describe a fluorescent quencher molecule.

2 Now, just as the en banc Federal Circuit in
3 Phillips found that steel baffles means baffles that are
4 not necessarily made of steel -- I'm sorry, I misspoke.
5 It says that steel baffles means that baffles inherently
6 are not necessarily made of steel. Likewise, here the
7 fact that the patentees talked about a fluorescent
8 quencher means that quencher molecules are not
9 necessarily fluorescent.

10 Similarly, the specification explicitly
11 states that quenchers can either dissipate the energy it
12 absorbed nonradiatively, or it can emit it at light.
13 However, Defendants are arguing that it must be required
14 to emit light.

15 Again, the specification shows in another
16 location, it talks about nonfluorescent quencher
17 molecules. It refers to them as chromogenic
18 molecules -- chromogenic molecules. In light of the
19 overwhelming intrinsic evidence, this is a simple task.
20 The word quencher means what it means. It means a
21 molecule that absorbs light from a reporter and then can
22 either emit that light as fluorescence, or it can
23 dissipate it nonradiatively.

24 What Defendants are doing are asking the
25 Court to rewrite the claims to say that quencher means

Page 9

1 something it doesn't mean. But the Federal Circuit is
2 clear, the Court --

3 THE COURT: Well, aren't they saying that
4 the patentee sort of at least implied that the quencher
5 molecules have to -- have to emit light --

6 MS. SCHMID: They're saying that --

7 THE COURT: -- by virtue of the comparison
8 between the fluorescence of the reporter and the
9 quencher?

10 MS. SCHMID: So using their mathematical
11 formulas, they're arguing that certain of the claims
12 would be -- would not make sense if a fluorescent --

13 THE COURT: Tell me why they would make
14 sense.

15 MS. SCHMID: Excuse me?

16 THE COURT: Tell me why they would make
17 sense.

18 MS. SCHMID: They would make sense because
19 the very term that they point to, that term itself
20 limits that particular claim to a nonfluorescent
21 quencher. However, it doesn't apply to all the other
22 claims.

23 Specifically, by having a ratio with a
24 non -- with -- with a quencher -- with the fluorescence
25 emitted from a quencher on the bottom, it's that very

Page 10

1 requirement that there is fluorescence from a quencher
2 that adds an additional limitation to that particular
3 claim that's not attached just to the word quencher.
4 It's attached to the location of the quencher on the
5 bottom of a fraction.

6 THE COURT: Well, are you telling me that
7 under those circumstances where a comparison or a
8 ratio is required that the quencher molecule in those
9 claims is necessarily one that is a fluorescent
10 quencher?

11 MS. SCHMID: Correct.

12 THE COURT: Okay.

13 MS. SCHMID: Plaintiffs believe the Court
14 should adopt the clear definition given in the
15 specification which is supported by the intrinsic
16 evidence and also reflects the plain and ordinary
17 meaning of the word quencher.

18 Moving on to the second term, a hairpin
19 structure. Both the parties agree that a hairpin
20 structure is a strand -- is when a strand of DNA loops
21 back and hybridizes with itself when certain basepairs
22 in different parts of the strand form bonds with each
23 other.

24 What the parties disagree about is what
25 other requirements should be included in the definition,

Page 11

1 and most particularly, whether or not the definition
2 should relate to the relationship of the reporter and
3 quencher.

4 Now, the patentees gave a definition of
5 hairpin structure in the specification. This is -- oh,
6 I'm sorry, this is a clear definition essentially saying
7 this is what hairpin structure means. In case there's
8 any ambiguity in the prosecution history, the patentees
9 represented that this very definition clearly defines
10 what is intended by hairpin structure.

11 Now, Defendants express some concern that
12 this is not the plain and ordinary meaning that just an
13 average biologist on the street would give to hairpin
14 structure, but there's two problems with this. First of
15 all, as we've discussed, Phillips says that a patentee
16 can act as their own lexicographer and give a word a
17 special definition, but what's further, the definition
18 that -- that the patentees have used in this case is a
19 definition that other people use in this exact field of
20 this type of probe. For example, one of the Defendants
21 in this case, Biosearch Technologies, has used the exact
22 definition in some of its own patents.

23 Further, this was not an accident that this
24 definition was used. This definition was specifically
25 used to distinguish over prior art in that there were

Page 12

1 pieces of prior art, such as Bagwell, that taught the
2 use of a hairpin structure for the purpose of bringing a
3 reporter and quencher molecule next to each other.

4 Plaintiffs are proposing one clarification
5 to the term from the specification. Particularly,
6 Plaintiffs are concerned that "proximity with" might be
7 confusing to a lay jury and propose clarifying this with
8 the slight phrase "next to." The reasons for this
9 clarification are based on the --

10 THE COURT: How about "nearby"?

11 MS. SCHMID: Yeah.

12 THE COURT: I mean, "proximity with" seems
13 to be -- to mean more than "next to" is what I'm -- what
14 I'm driving at.

15 MS. SCHMID: Uh-huh.

16 THE COURT: And I think the argument that
17 was made by the Defendants was that that was a more
18 restrictive definition than even what was found in the
19 patent. So if --

20 MS. SCHMID: We certainly are amenable to
21 other words to express the same concepts. The concept
22 that we're trying to -- to get across is sort of looking
23 at the prior art. I guess to put it in context, we
24 believe that the reason the Defendants are fighting so
25 hard to keep the relationship between the reporter and

Page 13

1 the quencher out is because probes will periodically --
 2 just certain bases somewhere on the probe might happen
 3 to be complimentary, but it's not going to impact the
 4 reporter and quencher.

5 But the -- the probes that the patentees
 6 were distinguishing over very specifically were designed
 7 to have this stretch of -- of complimentary basepairs
 8 specifically for the purpose of bringing the reporter
 9 and quencher next to each other.

10 So certainly if -- if the Court feels a
 11 different word would better express this, we would be
 12 fine with that. But we do believe that it's very clear
 13 from the intrinsic record that this is the prior art
 14 that led to this limitation, and that is what should be
 15 reflected.

16 So here's one example, whereas said
 17 hybridization is forming, here's the loop where it loops
 18 back on itself, and the reporter and quencher are
 19 brought next to each other. A second example, again,
 20 you have hybridization, a loop, and the reporter and
 21 quencher brought next to each other.

22 Coming from the notice of allowability, the
 23 examiner -- another word that Defendants (sic) would be
 24 amenable to is "together," which is the word that the
 25 patent examiner used. The patent examiner specifically

Page 14

1 noted that the closest prior art included Bagwell, et
 2 al, and that Bagwell was distinguishable because it
 3 taught a probe designed to form a hairpin that is --
 4 when it is not hybridized to the target molecule as a
 5 means of bringing the reporter and quencher molecules
 6 together. So Defendants (sic) would also be amenable to
 7 the word "together."

8 THE COURT: You mean Plaintiff?

9 MS. SCHMID: I'm so sorry, the Plaintiffs --

10 THE COURT: It's all right.

11 MS. SCHMID: -- would also be amenable to
 12 the words "together." You would have to ask the
 13 Defendants what they would --

14 THE COURT: I suspect --

15 MS. SCHMID: -- be amenable to.

16 THE COURT: -- I'll hear a disagreement
 17 about that.

18 MR. JOHNSON: That's a fair assumption, Your
 19 Honor.

20 THE COURT: I don't want to get ahead of
 21 myself.

22 MS. SCHMID: The word "next to," there's
 23 support for that from the extrinsic record, Webster's
 24 Dictionary at the time.

25 Now, Defendant's construction cannot be

Page 15

1 correct because it would read a preferred embodiment out
 2 of the specification. Just to walk through to make sure
 3 this is clear, one of the embodiments disclosed in the
 4 '848 and other patents is what's called the P2 probe.

5 You can see, so the reporter and quencher are attached
 6 to the end Ts. You can see the sequences is TCGCA.

7 So then the examiner in an interview looked
 8 at this probe and thought it would form a structure, an
 9 examiner -- it's in the examiner's handwriting. They
 10 wrote it out, you know, TCGC, just like up here, and
 11 they noted, look, here's the probe. It will go along,
 12 and then suddenly it will loop back, and this A might
 13 bind with this T. These two would not be complimentary,
 14 but this one is complimentary, this pair is
 15 complimentary, this pair is complimentary, this pair is
 16 complimentary. Oh, look, there's four complimentary
 17 basepairs that are contiguous.

18 So under Defendant's construction, this
 19 would be a hairpin. Under Plaintiffs', it would not,
 20 because the reporter and quencher on those two Ts, they
 21 would not be brought together. So -- and Defendants
 22 have admitted that under their construction this would
 23 form a hairpin.

24 So why is this relevant? Because the claims
 25 include hairpin as a negative limitation, that is, they

Page 16

1 claim probes which do not hybridize to form a hairpin.
 2 So, in other words, they claim probes that would not do
 3 this, but this probe is a preferred embodiment. And as
 4 the Federal Circuit has made clear, terms -- claim
 5 constructions that exclude preferred embodiments from
 6 the scope of the patent claim, not from the scope of the
 7 term, but from the scope -- scope of the patent claim
 8 are strongly disfavored.

9 For these reasons, Plaintiffs propose that
 10 the Court adopt the definition given by the patentees in
 11 the specification with the clarification of "next to" or
 12 another word that the Court prefers that expresses the
 13 same concept -- expresses the proper concept with for
 14 "proximity with" that the patentees and examiner were
 15 discussing in the intrinsic record.

16 The third term involves separation between a
 17 reporter and quencher molecule. The dispute here is
 18 what part of the specification to look at. Do we look
 19 at the part of the specification that uses the word
 20 separation, which is the same word used in the claim
 21 term, or do we look at parts of the specification that
 22 talk about nucleotide positioning and naming?

23 Now, one quick notation, this underlining,
 24 this is something that I -- I believe both the parties
 25 will be using, that essentially means the term appears

Page 17

1 in slightly different formats.

2 THE COURT: Yeah.

3 MS. SCHMID: Okay. Now, the part of the
4 specification that talks about separation, the word used
5 in the claim, defines that a separation of about 6 to 16
6 nucleotides is achieved by attaching one member of a
7 reporter pair to a five prime end of a probe and the
8 other member to a base 16 -- 6 to 16 nucleotides away.
9 So when it says, away, grammatically what it's referring
10 back to is the five prime end of the probe.

11 So what is a five prime end of a probe?
12 When the claims talk about ends of probes, they're
13 talking about the terminal nucleotides of a probe, and
14 that's consistent with the Defendant's understanding,
15 what they presented in their tutorial to this Court,
16 where they show a reporter and a quencher both attached
17 to the end of a probe right here at the terminal
18 nucleotide.

19 So what this slide is saying is this
20 separation is achieved by attaching, for example, a
21 reporter to the five prime nucleotide of the probe and
22 the other member to a nucleotide 6 to 16 nucleotides
23 away from that first nucleotide.

24 What does this look like in practice? The
25 patentee showed us in the prosecution history. They

Page 18

1 characterize a reference, Lee, et al, and explain that
2 in this reference, the reporter and quencher, the
3 quencher here is called an acceptor, are separated by
4 seven nucleotides.

5 So you can see here is the reporter. It's
6 attached to the five prime terminal nucleotide, and then
7 counting one, two, three, four, five, six, seven away,
8 the quencher is attached. Likewise, below it, the
9 reporter is attached to this terminal nucleotide, and
10 then one, two, three, four, five, six, seven away from
11 that five prime nucleotide, the quencher is attached.

12 Defendants have not denied that this is what
13 it teaches in the prosecution history.

14 Now, Defendants also point to the
15 specification, but the point -- the part of the
16 specification they point to doesn't use the word
17 separated or separation, which is the word of the claim.
18 Instead, it talks about naming and it talks about
19 nucleotide position. They give no reason for why a
20 patentee might not choose to act as a lexicographer for
21 a different word separate -- separation and use
22 separation notation for both.

23 For these reasons, Plaintiffs believe the
24 Court should adopt the definition given in the
25 specification for separation, which is supported by the

Page 19

1 prosecution history.

2 So those are the first three claims, all of
3 which the patentee defined in the specification.

4 We're now going to talk about the next two
5 claims which do not require construction.

6 As a reminder, the Federal Circuit has
7 emphasized that a term does not need to be construed
8 just because one party asked for it to be construed, but
9 rather it should be construed where there -- the
10 meanings would need clarification or where construction
11 is necessary to aid in the determination of infringement
12 or invalidity.

13 If we look at term four, terminal
14 nucleotide, the Defendants have used the word terminal
15 nucleotide in their proposed construction admitting that
16 the words themselves, terminal and nucleotide, will not
17 be confusing to a jury.

18 Further, they have not identified any
19 concrete dispute related to invalidity or infringement
20 that requires construction of this term. They have
21 generally stated that there -- there is a dispute but
22 refused to identify what it is. So either they're
23 asking this Court for an advisory opinion, or they're
24 intentionally hiding the ball and refusing to identify
25 why there's a dispute about this term.

Page 20

1 Further, the -- if the Court should decide
2 to construe terminal nucleotide, it should do so with
3 the plain and ordinary meaning, which is shown by
4 looking through the intrinsic record as the end monomer
5 of an oligonucleotide. We say this because when
6 terminal nucleotides are discussed --

7 THE COURT: You may want to slow down a
8 little bit with the --

9 MS. SCHMID: Oh, I'm sorry.

10 THE COURT: -- the nucleotide terms.

11 MS. SCHMID: Big words.

12 THE COURT: She's -- well, she's trying to
13 keep up.

14 MS. SCHMID: Definitely, please, if I talk
15 to fast again, yell at me.

16 So the claims show that when the patentees
17 discussed terminal nucleotides, they're talking about a
18 nucleotide on the end of the probe, which the probe
19 relates to an oligonucleotide probe, and in the
20 specification, it shows that probes are oligonucleotide
21 probes.

22 And the parties have agreed on language that
23 was taken from a definition in the specification that an
24 oligonucleotide is a linear array of monomers. So
25 putting this together, a terminal nucleotide would be

Page 21

1 the last of these monomers on the line, so the end
2 monomer of an oligonucleotide.

3 Over all, though, Plaintiffs believe that no
4 construction of this term is necessary because
5 Defendants used the very word of the term in their
6 construction, and they have not identified any dispute
7 relevant to this term.

8 The next term at issue is monitoring the
9 fluorescence. The dispute between the parties first is
10 should this claim be construed at all, and if so, should
11 the Court add limitations to the plain and ordinary
12 meaning?

13 Defendants are proposing adding two
14 limitations. Note -- it's worth noting they, again, use
15 the exact same language, recognizing that a jury will
16 understand what monitoring means and a jury will
17 understand what fluorescence means.

18 But what they want to add is that the
19 monitoring has to happen at a particular wavelength,
20 and, also, they want to add that you can't start
21 monitoring until the reaction is done.

22 Now, for the first limitation that the
23 monitoring has to happen at a particular wavelength,
24 this is contradicted by the specification. The
25 specification shows an example that monitors at two

Page 22

1 wavelengths, 518 and 5 -- and 582. Plaintiffs pointed
2 this out in their opening brief, and Defendants did not
3 deny that this is disclosed in the specification.

4 Similarly, Defendant's second proposed
5 limitation that you have to wait until a reaction is
6 over before you can start monitoring it is also
7 contradicted by the intrinsic record. Specifically, the
8 specification that the patents cite to a reference by
9 Higuchi, et al, which was published in 1992, that's two
10 years before the first patent in this family was filed,
11 and this reference discusses continuous monitoring of
12 PCR, and it just describes taking an off-the-shelf
13 fiberoptic device and using that to monitor the
14 fluorescence throughout the reaction.

15 The specification also cites to another
16 reference, also by Higuchi, et al, this one published in
17 1993, one year before the filing of the first
18 patent-in-suit, which also describes continuous
19 monitoring of fluorescence, this time using an
20 off-the-shelf video camera.

21 Now, in order to deny that fluorescence
22 monitoring was done, Defendants try to mischaracterize
23 some extrinsic references. Specifically, they look to
24 some marketing materials published after the patents
25 that talk about -- that discuss monitoring. And they

Page 23

1 take some words out of context, when what this -- what
2 these articles are really talking about, you know, one
3 of them is -- is marketing material and may include some
4 words about the importance that -- the marketing
5 materials may include some words that seem a little bit
6 like hyperbole, but that kind of language --

7 THE COURT: In marketing materials? You're
8 kidding me.

9 MS. SCHMID: That kind of language is common
10 in marketing materials.

11 And, likewise, they cite a scientific paper
12 which discusses the introduction of a new machine, and
13 what was really important in this machine, the goal was
14 to develop high-throughput methodology for doing this.
15 So they weren't saying that before 1996, no one had done
16 this before. They were saying their goal was to come up
17 with something high-throughput, and that their machine
18 allows you to do 96 samples at the same time.

19 So Higuchi, et al, were sitting there, you
20 know, with their little fiberoptics and their video
21 cameras, and they could do a couple of samples, but now
22 this new machine launched by Applied Biosystems allows
23 96 wells at the same time.

24 Now, if the Court does believe the term
25 needs construction, Plaintiffs believe the Court should

Page 24

1 adopt the plain and ordinary meaning, which is checking
2 on the fluorescence during the reaction. This is
3 supported by the intrinsic record which shows real-time
4 monitoring of an amplification reaction and that
5 monitoring was happening during the reaction.

6 So in summary, Plaintiffs believe that no
7 construction is required. The Defendants used the words
8 of the terms in their constructions, and the -- their
9 proposed limitations are contradicted by the intrinsic
10 record.

11 Moving on to the last three terms at issue
12 here, terms six through eight, Defendants argue that
13 these terms are means-plus-function terms, however,
14 they're not.

15 As a quick review of means-plus-function
16 law, the Federal Circuit has made clear that if the word
17 means is not present, there is a strong presumption
18 that's not readily overcome that the claims are not
19 means-plus-function.

20 In order to overcome this presumption,
21 they -- Defendants essentially need to show that the
22 claim is completely lacking in structure. As the
23 Federal Circuit said in the Lighting World case, it is
24 sufficient for us, the Plaintiffs, if the claim term is
25 used in common parlance or by persons of skill in the

Page 25

1 pertinent art to designate structure, even if the term
2 covers a broad class of structures and even if the term
3 identifies structures by their function.

4 Now, this Lighting World case is an
5 important case. In this case, the Defendants that
6 argued that a term was means-plus-function, they even
7 submitted an expert declaration claiming that the word
8 had no specific structure, and the Court -- the Federal
9 Circuit overturned the district court's ruling that this
10 was a means-plus-function term holding that even with an
11 expert declaration, the expert had used the wrong
12 standard because the expert was looking for one specific
13 concrete structure when really a broad class of
14 structures is fine as long as persons of skill in the
15 pertinent art would recognize it as a structure.

16 So as the Court said in Phillips,
17 means-plus-function claiming applies only to purely
18 functional limitations.

19 So some examples of limitations that the
20 Federal Circuit has found do not invoke
21 means-plus-function include aesthetic correction
22 circuitry, connector assembly, reciprocating member,
23 detent mechanism.

24 Looking at the -- the term at issue here,
25 this claim term is not means-plus-function because it

Page 26

1 designates a specific structure, oligonucleotide probe
2 or oligonucleotide sequence. Now, these two words are
3 used interchangeably by those of skill in the art,
4 oligonucleotide sequence and oligonucleotide probe.

5 Now, how do we know it's a structure?
6 First, we know because Defendants agreed to a definition
7 of oligonucleotide that was given by the specif -- by
8 the patentees in the specification, and in this
9 definition, it's a structure. It's a linear oligomer of
10 natural or modified monomers or linkages. We also know
11 because it says so in the specification.
12 Oligonucleotide probes of the invention can be
13 synthesized by a number of approaches. So this is
14 something that can be made. It's not some theoretical
15 etherial means of creating fluorescence.

16 We also know because Defendants showed in
17 their tutorial this is a probe. It has a structure.
18 You can see it. This is the probe in one confirmation.
19 It changes confirmation, but it's the same structure.

20 And, again, just to highlight, the Court
21 this time in Crane has said, the fact that a term is
22 broad and might include almost an infinite number of
23 structures did not render the limitation
24 means-plus-function.

25 This is important because Plaintiffs have

Page 27

1 not been able to cite to any case that discusses
2 oligonucleotide sequence, probes, DNA, RNA, that says
3 that they're actually means-plus-function. So instead,
4 they try to argue that because the sequence of an
5 oligonucleotide can be different, it can't be a
6 structure because there could be so many different
7 possible structures, which is why it's so important that
8 even an infinite number of structures...

9 So to think about it another way, in the CCS
10 case, the Court found that reciprocating member was not
11 means-plus-function. Now, reciprocating member,
12 those -- you know, it's well known in the art what a
13 reciprocating member is, but they can still come in all
14 sizes. You know, you can imagine if you're just going
15 up and down tiny, tiny amounts, there could be an almost
16 infinite number of sizes. Yet still, they say one of
17 skill in the art can pick out the right size, figure out
18 what's going to work, and make it work.

19 Now, because there's no case -- case law
20 supporting them, additionally, really the only evidence
21 that they're saying this is not a structure is attorney
22 argument. They haven't brought forward any expert
23 declarations claiming that one of skill in the art would
24 not know what an oligonucleotide probe is.

25 So instead, they rely entirely on one case

Page 28

1 from the District of Delaware which differs from this
2 case. This case talks about a type of circuit. I
3 believe it's a soft-something circuit. I'm blanking on
4 the other word, but in this Court -- in this case, even
5 in this case, it particularly distinguishes its own case
6 from the Federal Circuit case of Linear, because in
7 Linear, circuit was found not to be means-plus-function
8 because it was sufficiently coupled with a description
9 of the circuit's operation.

10 Likewise, in this case, not only is
11 oligonucleotide probe or oligonucleotide sequence a
12 sufficient structure on its own, the term also includes
13 other language that's description of the probe.

14 Finally, other cases in addition to Linear
15 employ the same reasoning, that the claim language here
16 is -- does not merely describe a circuit. It adds
17 further structure by describing the operation of the
18 circuit, which is exactly what's happening in these
19 terms. They provide further description about the
20 operation of the probe.

21 Plaintiffs' next -- the next term to be
22 construed -- or I guess in summary, first, the term
23 we're looking at, the said oligonucleotide term, term
24 six, it's not means-plus-function because it lacks the
25 words means creating a strong presumption that it's not

Page 29

1 means-plus-function, and it also includes specific
2 structures of oligonucleotide probe and oligonucleotide
3 sequence.

4 The next term is similar. It's a long term.
5 Defendants are arguing that it's means-plus-function.
6 In the alternative, they're arguing that it's too
7 indefinite or ambiguous to interpret. And, finally, a
8 second alternative, they propose a specific construction
9 in which they propose importing limitations from a
10 single example.

11 None of these approaches should be adopted.

12 Just as with the previous term, this term
13 has a structure, and you can see the structure right
14 here. It's oligonucleotide sequence, and we know that
15 oligonucleotides are -- oligonucleotide sequences are
16 structures for all of the same reasons we discussed. We
17 also know that the term is not indefinite because
18 Defendants did not contest that optimization was well
19 known in the art at the time these patents were filed.

20 Additionally, the law is that a claim cannot
21 be indefinite if the meaning of the claim is discernible
22 even if it would be difficult to come up with a meaning
23 for it. Now, Defendants can't have it both ways.
24 They're trying to say it's indefinite, but then they're
25 also proposing a construction. So it's got to be one or

Page 30

1 the other, and by admitting that there's a possible
2 construction for it, Defendants are showing that the
3 claim term is not indefinite.

4 However, the ultimate construction that
5 Defendants are proposing imports the limitations from
6 one particular example which Phillips has said clearly
7 you cannot do. So in sum, this term is not
8 means-plus-function because it lacks the word means and
9 because it includes specific structures. It's not
10 indefinite, and it also -- Defendant's proposed
11 construction improperly imports limitations from a
12 single example, should be rejected, and no construction
13 is required because Defendants have not identified any
14 words in this claim that -- that they consider confusing
15 or that a lay jury would not understand.

16 The last term is very similar. Defendants
17 are, again, arguing that this term should be
18 means-plus-function. In the alternative, that it's
19 indefinite or in the second alternative that it should
20 have one particular construction that imports
21 limitations from a single example.

22 Just as before, though, this term also
23 includes structures of -- lower down -- the probe and
24 the oligonucleotide sequence. But both oligonucleotide
25 probes and oligonucleotide sequences are well known

Page 31

1 structures in the art. The term is not indefinite
2 because Defendants have not disputed that optimization
3 was well known in the art at the time the patents were
4 filed and because the standard for indefiniteness is
5 higher than Defendants have met, and, finally, because
6 their construction is improper because it improperly is
7 importing limitations in from a single example.

8 So we covered a lot. So as a quick review,
9 the first three terms should be construed as the patents
10 defined them in the specification. The second terms do
11 not require construction because the patentees admit
12 this by using the very terms in the definition. And the
13 final terms are not means-plus-function because they do
14 not include the word means because they disclose
15 structures, they are not indefinite, and they do not
16 require construction.

17 THE COURT: How would one of skill in the
18 art go about measuring the ratio of the fluorescence's
19 intensities as called out in, say, the last term?

20 MS. SCHMID: In -- so the measurement of
21 fluorescence is something that was well known in the
22 art. You know, in addition to the examples provided in
23 the patent, the example cited in the intrinsic record,
24 including the Higuchi paper, disclosed measuring of
25 fluorescence, and then once fluorescence is measured,

Page 32

1 the comparison of whether or not it's six times greater
2 is even -- I believe table -- it's disclosed in the
3 patent specification. I don't have the exact table in
4 front of me, but when you have two numbers just
5 comparing them to see if they're six times greater or
6 not.

7 THE COURT: Well, I think their argument,
8 though, as I understood it, was that that ratio depends
9 on the conditions under which you're measuring the --
10 the fluorescence, correct?

11 MS. SCHMID: Correct.

12 THE COURT: So if I alter the solution that
13 I'm examining for taking measurements and make the ratio
14 not six times, have I -- do I infringe or not?

15 MS. SCHMID: So as described, for the
16 indefiniteness argument, optimization of reaction
17 conditions was well known in the art. People running
18 these PCR reactions knew all the different variables and
19 conditions and knew how to optimize them.

20 In fact, the very figure that Defendants
21 show where they show the impact of magnesium and how it
22 can change and impact figures, that shows how those of
23 skill in the art knew how to test and optimize different
24 conditions.

25 THE COURT: Okay.

Page 33

1 MS. SCHMID: So what one of skill in the art
2 would have understood the patent to be saying is
3 optimize a reaction, then you take the fluorescence in
4 that reaction, you got another reaction, optimize that
5 reaction, take the fluorescence in that reaction,
6 compare the fluorescence of the two and see whether it's
7 six volts higher or not.

8 THE COURT: So is the answer to my question,
9 yes, it would infringe, or, no, it would not infringe if
10 I was able to alter the properties of the solution such
11 that the ratio was not at least six times as called out
12 in the claim?

13 MS. SCHMID: No, it would not infringe.

14 THE COURT: Okay. All right.

15 MS. SCHMID: And if there are no further
16 questions, I reserve time for rebuttal.

17 THE COURT: Thank you.

18 MR. JOHNSON: Morning, Your Honor.

19 THE COURT: Good morning.

20 MR. JOHNSON: I think we've got ours. I'm
21 going to move through some of these fairly quickly since
22 the overview is already done, and I don't want to waste
23 your time. So --

24 THE COURT: I mean, you take what time you
25 need.

Page 34

1 MR. JOHNSON: I understand. I understand.

2 THE COURT: You're not -- you're not wasting
3 my time.

4 MR. JOHNSON: All right. So we've already
5 gone through and talked about the basic DNA structures.
6 You're familiar with that. And we've talked about FRET,
7 which you're also familiar with, and DNA detection,
8 which we've already gone through.

9 So if we go over to our summary, and
10 obviously we have a very different view of what
11 constitutes monitoring of fluorescence, we don't think
12 it is, quote -- there was a, quote, optimization that
13 was new -- that was understood. We think that the
14 patent has very specific requirements for determining
15 fluorescence which cannot be simply ignored.

16 The same is true with quencher molecule and
17 how it's supposedly defined. We think that the quencher
18 molecule that they, in fact, are claiming is one that
19 requires fluorescence, and we'll point out to the Court
20 why we believe that to be the case.

21 Let's go to the next slide.

22 This hairpin structure, the critical point
23 to be made on hairpin structure is they are defining
24 hairpin structure as a probe, and it -- and the patent
25 makes it clear that it's not a probe, that you don't

Page 35

1 have a reporter and you don't have a quencher. You have
2 a particular structure which we will discuss. And
3 that's why there's this dispute between the parties
4 because they're using language that talks about a probe
5 when they very clearly told the Patent Office it was
6 not.

7 The issue of separation of reporter and
8 quencher we're going to discuss. Also, why we think the
9 term terminal nucleotide has to be defined. And then
10 we're going to go through this ratio issue, again, for
11 the Court because we think it is -- it is going to be
12 critical to the understanding of the issues the jury's
13 going to have to decide.

14 Next slide.

15 Again, abbreviation of what is an -- is
16 existing is something we're -- we think the Court needs
17 to focus on for purposes of claim construction.

18 And so let's start with monitoring of
19 fluorescence. So -- and, oh, by the way, I do
20 apologize. I didn't say, I'm -- I'm Dan Johnson, and
21 I'm here on behalf of Biosearch.

22 So when we're talking about monitoring the
23 fluorescence, while the other side says it doesn't
24 require any interpretation, we say that monitoring the
25 generation of fluorescence at a particular wavelength

Page 36

1 only at the conclusion of an amplification reaction.
2 Why is that? That's because of the state of the art
3 that existed as of the time this patent was filed for.

4 And we cite the PC Connector case, as well
5 as Phillips, for the proposition you can't claim the
6 existence of an invention when a portion of what you are
7 claiming was not invented yet. You have to show -- you
8 have to be limited to what was the testing being done at
9 the time.

10 THE COURT: Didn't PC Connector have in the
11 claim language itself a temporal limitation to
12 contemporary or existing technologies?

13 MR. JOHNSON: That's true, it did. However,
14 in this -- we -- we actually have the same thing in the
15 situation before this Court, and it's found in their
16 example in the -- it's in all of the patents, but we can
17 look specifically at the -- the '591. So, for example,
18 let's go to the next -- next slide, we talk about --
19 back up for a second. One slide before.

20 In their example -- in the -- in the patent
21 itself, they talk about the desirability of this
22 real-time PCR, and you say, okay, well, that's -- that
23 would suggest that this is something we'd like to do,
24 but -- so what you have to do is look at, in fact, what
25 they did.

Page 37

Page 39

1 If we go to the next slide, here's what
 2 we're talking about. They actually have a specific
 3 recipe for how you go about this monitoring, and it
 4 required specific equipment. Whether you have that
 5 specific equipment or not is not important. But they
 6 had two target genes they were using. They had a
 7 specific recipe, which included magnesium concentration.
 8 And I know you just heard everybody knew how to
 9 optimize. Well, I fundamentally disagree with that. If
 10 they knew how to optimize, there would be no need for
 11 this patent and there would be no need for all the
 12 research that was being done trying to figure out how
 13 you could get these probes to work in the proper
 14 fashion.

15 They also had specific target sequences
 16 closed -- disclosed. They gave you specific times and
 17 specific temperatures you had to do certain acts. And,
 18 finally, they had to tell -- they told you and disclosed
 19 when this monitoring was to be done.

20 And if we go to the next slide, Your Honor,
 21 if you go to Column 19 of the '591, you find their,
 22 quote, method for monitoring PCR amplification. I know
 23 you just heard that there -- that these shouldn't be
 24 means-plus-function, but here is exactly what they
 25 told -- told you to do. And they didn't have any other

1 transferred to an individual well. That means it was at
 2 the end. You put it in a separate machine of a white
 3 96-well microtiter plate, and then fluorescence was
 4 measured. That's end time PCR. Their end time
 5 analysis, that is the only disclosure in this patent
 6 that tells one of ordinary skill in the art how to do
 7 what they are claiming.

8 Now, they would say, well, that's just one
 9 example. That's the only example. There is no
 10 disclosure of how to do anything approaching real-time
 11 PCR in this patent. And the reason this is important,
 12 and it goes to this whole ratio issue, because they, in
 13 effect, have laid out exactly how you were supposed to
 14 do the -- the analysis, and that is contained in their
 15 patent. They don't -- and they would like to expand it
 16 to include real-time so they can ensnare future
 17 technology. But this is what they disclosed.

18 Now, the language --

19 THE COURT: But is it a claim construction
 20 question, or is it a written description issue?

21 MR. JOHNSON: You know, I have to tell you
 22 the truth, I battled that issue. We have argued --

23 THE COURT: Me too.

24 MR. JOHNSON: We have argued over that. I
 25 can tell you that my view of the world is that it's

Page 38

Page 40

1 examples.

2 In that method, they I told you what the
 3 target gene was. They told you the specific magnesium
 4 concentration. And we pointed out why that's so
 5 important because you -- the results will change
 6 radically depending upon that magnesium concentration.
 7 It's also going to change based upon the cycle time.

8 Go to the next slide.

9 And over here we have the second gene, and
 10 you'll see a different magnesium concen --
 11 concentration, a different cycle time. And this is
 12 important because if you were somebody of ordinary skill
 13 in the art, you'd have to know this recipe, otherwise,
 14 you're just experimenting.

15 And therein lies their problem. They want
 16 to say it's obvious or it's clear, but in order to do
 17 this analysis -- and then what's the analysis? To
 18 figure out the fluorescence so that you can determine if
 19 the probe is successful or not, you have to go through
 20 these steps.

21 The next slide, please.

22 So we talked about -- you heard them talk to
 23 you about the issue of end time analysis as opposed to
 24 real-time, this is what they disclosed. They disclosed
 25 for amplification reaction 40 milliliters was

1 both, and the reason it's both is because of the way
 2 they drafted the language.

3 Now, you know, obviously, you know where
 4 we're -- we're going to end up filing a motion for
 5 summary judgment at some point, but I think it's claim
 6 construction because monitoring, if it meant any type of
 7 monitoring, would necessarily imply that all aspects of
 8 monitoring were known to somebody of ordinary skill in
 9 the art, and what we're saying is, you very clearly
 10 understood what monitoring was, you disclosed it, and it
 11 was end point monitoring.

12 THE COURT: Well, what's your answer to
 13 their references that were incorporated?

14 MR. JOHNSON: The references that were
 15 incorporated discussed the concept of doing real-time
 16 monitoring, but there was nothing in the patent or even
 17 in the references they cited that showed you this was
 18 the way one would do it. That was a suggestion of how
 19 one might do real-time PCR. That's fundamentally
 20 different.

21 And as we point out in our papers, their
 22 claim that it was known is rebutted by the fact that
 23 nobody did it. And that if they, in fact, had believed
 24 there was a way to do it, instead of using the words
 25 like desirable, they would have -- just like they did

Page 41	Page 43
<p>1 with their recipe for the end point, they would have 2 given us a recipe, but no such recipe was given. And we 3 are convinced that a recipe was critical in this case 4 because we're not talking about opening up a can of soup 5 here. We're testing for probes to determine genetic 6 makeup and genetic issues. That could not be done just 7 simply by anybody walking down the street. 8 The next slide. 9 The -- the argument they make about, well, 10 we could do it 96 times, and so, therefore, this was a 11 different probe, if you go back two slides -- go back 12 two slides to the quote that I gave you -- there's a 96 13 well microtiter plate that they had disclosed. So that 14 obviously was not the differentiator. It wasn't 96. It 15 was the difference between end point and real-time. 16 Go back -- go forward, please. 17 Now, we discussed the Higuchi reference and 18 why there is no disclosure at that point to establish 19 what ultimately became real-time PCR. We believe 20 there's -- their subsequent statements that, in fact, 21 they invented it years later is, in fact, correct, but 22 that in any event, they were obligated to disclose to 23 someone of ordinary skill in the art how to accomplish 24 this particular result, and they did not. 25 Next.</p>	<p>1 some form of quenching, which as I understand it, would 2 still result in a finding that there had to be some 3 fluorescence, because, otherwise, they would have, in 4 effect, invented what became known as the dark quencher, 5 and they never say that -- they never used the word 6 substantially because they gave it up, and they never 7 used the words totally because they never claim it. 8 Our view of the world is this is the best 9 evidence that we were right when we said looking at the 10 formula, fluorescence greater than 0 is required. 11 Next slide. 12 And we've gone through the analysis. You 13 can't have -- you can't get to this greater than six 14 number without having the ability to do a calculation. 15 And doing that greater than six calculation requires you 16 to look at the ratio of the various -- of the 17 fluorescence, and you can't have 0 in the denominator. 18 Now, they say, well, we're trying to rewrite 19 the claim. We're not. We're saying, you knew you 20 couldn't get substantially quenched, so when you went to 21 quenched, you necessarily ended up in a situation where 22 you could not end up with a quencher that did not emit 23 any light whatsoever. 24 Next slide. Next slide. Next Slide. 25 Hairpin structure. Now, hairpin structure</p>
Page 42	Page 44
<p>1 All right. Quencher molecules, the Court -- 2 I heard the admission that they concede that at least as 3 to certain claims, the fluorescence is required because, 4 obviously, if you get to 0, you get a nonsensical 5 result. I'm not going to belabor the point other than 6 to say that as far as we're concerned, that's the only 7 result they can get, and the reason is because they are 8 measuring fluorescence -- in those instances where 9 they're measuring the fluorescence between the quencher 10 and the reporter, it has to be done in a certain way. 11 And why is that important? It's important because -- 12 Let's go to the next slide -- in the -- one 13 more slide, please, keep going. 14 In their file wrapper, they said in one of 15 their earlier -- earlier proposals that this quencher, 16 all it had to do was, quote -- quote, substantially 17 quench. That's in the wrapper in their original claim 18 for the -- original Claim 1, and that's at Exhibit U. 19 The examiner rejected it saying, wait a second, 20 substantially, under 35 U.S.C. 112, is indefinite 21 because it does not allow to determine the metes and 22 bounds of the invention. 23 Now, if substantially quenches doesn't do 24 it, they removed it and put it in quenching, they didn't 25 ask for total quenched or completely quenched, it is</p>	<p>1 is interesting, Your Honor. We call it a single 2 stranded oligonucleotide sequence that is hybridized 3 with itself to form a double stranded duplex of three or 4 more contiguous basepairs at the detection temperature 5 of the assay. 6 Now, the Plaintiffs' proposal, and they 7 quote from the patent, and this is very important, what 8 they did was they quoted from a reference to prior art 9 in the patent, and it says, where the probe hybridizes 10 to itself to form a loop. Now, so you see their 11 language, it was a probe that was hybridizing to itself. 12 Obviously, then the -- with the reporter and the 13 quencher molecule close together, and then they said, 14 next to. Let me show you what they said in the file 15 wrapper. 16 Can you guys throw that up? 17 Let me just put it on the ELMO. 18 This is their Exhibit G, Your Honor. Let me 19 see if I can get it big enough so you can see it. 20 THE COURT: It's their Exhibit G? 21 MR. JOHNSON: Their Exhibit G. They 22 specifically say, it is clear that applicants intended 23 probes which do not hybridize with themselves to form a 24 hairpin structure to fall within the scope of the 25 present invention. They go on to say -- and that's at</p>

Page 45

1 Page 3, Your Honor, of Exhibit G.

2 THE COURT: I'm with you.

3 MR. JOHNSON: And you keep going, it says,
4 the intention of applicants to exclude probes which are
5 designed to form hairpin structures is made clear by
6 applicants teaching away from the use of probes with a
7 hairpin structure. And the reason they taught away from
8 it is because it -- it had some inherent deficiencies.

9 Specifically, the specification teaches that probes,
10 including hairpin structure, had the disadvantage that
11 they can be difficult to design and may interfere with
12 the hybridization of the probe to the target sequence.

13 And if you go over to the next page, you'll
14 see the following language. In view of the various
15 teachings in the specification, applicants maintain that
16 clear support is provided for the phrase, an
17 oligonucleotide sequence which does not hybridize with
18 itself to form a hairpin structure, and respectfully
19 requests that the examiner withdraw the present
20 rejection under 35 U.S.C. 112, first paragraph.

21 Well, you can't come -- you can't tell the
22 examiner, our hairpin structure did not include probes.
23 We taught away from probes, and we defined it exactly
24 the way the Defendants have defined it, save and except
25 for I'm going to talk about the double stranded duplex

Page 47

1 When we looked at all of the examples in the
2 patent, we saw that that base was at least three. It
3 could be more than three, but it had to be at least
4 three. And that stem portion, in our view, is supported
5 by looking at the examples they gave us in -- in the
6 record.

7 Okay. Now, let's go back to Slide 35, I
8 guess.

9 Now, it is true that the specification does
10 not define the number of basepairs. However, our view
11 is that in order to have a proper structure, you've got
12 to have at least three basepairs. If you've got less
13 than that, it's not going to be a proper structure.

14 Next slide.

15 Now, we point to their examples. You see
16 Figure 4, again, you see the -- the three lines, or in
17 one case four, those are basepairs. Those are connected
18 together.

19 In their -- in their definition during the
20 prosecution, they said a hairpin consists of a basepair
21 double-helical region, the stem, with a loop of unpaired
22 bases at one end. And, again, you see the stem. That's
23 why in our view, our definition requiring the three
24 basepairs is important, but the most important thing is
25 it cannot be a probe.

Page 46

1 of three or more contiguous pairs, because they can't
2 claim a probe as being a hairpin. They gave that away.

3 Now, the question is proximity is not the
4 same as next to. And you're absolutely right. Prox --
5 words like proximity, nearby, make a lot of sense in
6 connection with the -- the probes we're talking about.

7 They're going to beat me up, but I
8 apologize. Go back to the language -- go back and show
9 me the slides where we have the DNA examples right at
10 the beginning.

11 Okay. Let's go -- keep -- flip it forward.

12 You see, this is an example, Your Honor, of
13 a hairpin structure. Two things to point out. Number
14 one, the base or the stem, they are proximately nearby,
15 but that's not necessarily next to or touching. Why
16 that's important has to do with this.

17 If I can walk over, I can explain a little
18 better.

19 Basically, if you view this as a balloon
20 where you've got a string at the bottom, that string is
21 the stem. If the stem is too small, you don't end up
22 with a hairpin, you end up basically with a circle, and
23 it has certain implications for the performance. So
24 you've got to have a big enough base or a long enough
25 base to make it work.

Page 48

1 Next slide.

2 All right. Now, I suppose people can argue
3 about everything, but here our position is very clear.
4 In the argument -- in the -- in their disclosure where
5 they say A1 to A7, the math is very simple. They
6 count -- go to the next slide -- you've got to count the
7 nucleotides. So you start with your reporter, then you
8 go to the quencher. Their examples in our view all
9 support that, and there's no example where you exclude
10 the reporter and include the quencher, which is what
11 they are proposing.

12 Obviously, if you do the math, and it's
13 supposed to be 15 nucleotides apart, it works for us.
14 It doesn't work if you exclude the reporter, and then
15 you're left with -- with just 14.

16 Next slide.

17 Terminal nucleotide. Why is that important?
18 That's important because when you look at the
19 specifications for the '591, as well as for the '848 --

20 THE COURT: Well, let me go back to the
21 previous term.

22 MR. JOHNSON: Yes.

23 THE COURT: I mean, you agree that the
24 prosecution history example shows something different
25 from what you're arguing?

Page 49

Page 51

MR. JOHNSON: I -- I've got to see that example and have it in front of me. I don't...

Do we have that -- let me grab their slides and look at them.

I think we're at Page 32 of their slide, Your Honor.

THE COURT: I was on Page 18 of their brief, but...

MR. JOHNSON: So their slide, which is what I think it is, yeah.

THE COURT: Yes.

MR. JOHNSON: Yeah, and in that scenario, they, in fact, are counting both, as I understand it. They say they are separated by seven, but if you do the math, it's one, two, three, four, five, six, seven, in the eighth one, the E is the quencher.

THE COURT: Correct. So they don't count the reporter, but they do count the quencher?

MR. JOHNSON: Well, or they -- either that, or they count the -- the reporter but don't count the quencher. I mean, there's no way you can tell from this.

THE COURT: But in any event, it's separated by seven nucleotides?

MR. JOHNSON: Correct.

So the reason terminal nucleotide or terminal carbon is important is they make it very clear that if you don't want to attach it to internally, you want to attach -- attach it at the terminal.

So now what is the terminal either nucleotide or carbon? Our view of the world is that in order for this jury to have an understanding, it's got to be defined because there are lots of things on those ends of the -- of these particular strings that need to be defined.

Our -- and so that's why we defined it to include a base, a ribose with deoxyribose structure and phosphate or modified phosphate structure.

Plaintiffs then said, well, but you have to include ribose or deoxyribose structures. We don't care. We -- but if you don't define it this way and if you just say it's a terminal nucleotide, you say too much, because, in fact, there are specific end points. It's either going -- you call it a carbon, you're going to be looking at these things.

What we've done here is try to make it clear what is at that terminal point. And that's all we're trying to accomplish here. We don't believe the notion that it -- it doesn't have -- it's entitled to its plain and ordinary meaning makes a lot of sense.

Page 50

Page 52

THE COURT: Okay. And so, I mean, my question is this is different from what you're arguing, correct?

MR. JOHNSON: That is correct.

Now, the term terminal nucleotide, as I pointed out, as I was about to say, is in both of the two primary patents, in the first '848 -- in the '848, the language refers to the importance of having a term -- the attachment at the terminal, and the reason it's important, according to -- to the claim, is if you have an internal attachment, that creates problems you don't want. So that's -- this is what started it.

If you go back to the '848. If you want, I can get you the specific language, Your Honor. If you look at -- if you look at Column 5 of the '848, and if you go down to Lines 37 through 43, it says, preferably, the three prime terminal nucleotide of the oligonucleotide probe is blocked or rendered incapable of extension by a nucleotide -- a nucleic acid polymerase. Such blocking is conveniently carried out by the attachment of a reporter or quencher molecule to the terminal three carbon of the oligonucleotide probe by a linking moiety.

In the '591, they say the same thing except they call it an attachment to the terminal nucleotide.

Now, we get to the factor six. The problem with their argument is they spend all the time saying that, well, the oligonucleotide has a structure. And so, therefore, it's been disclosed. The problem with their argument is the issue is how do you figure out the ratio of the fluorescence of said reporter molecule and said quencher molecule when the probe is hybridized to a target polynucleotide, okay? And it's got to be, according to their -- to their claim, a factor of six.

So I've got to know -- first, I've got to be able to measure it and I have to be able to develop a protocol that results in at least a factor of six difference in intensity or I don't practice the patent.

How do I do that? Short answer is there's no way one can tell looking at the language of these claims. That's why we argue they have to be means-plus-function because they don't disclose sufficient detail to enable someone of ordinary skill in the art how to practice this invention. The only place in the patent that does is the previously-quoted recipe.

If they -- and if -- the argument that, well, you have a structure, you know it's an oligonucleotide. As we pointed out, an oligonucleotide can be all sorts of things, but more than that, you have to figure out how to get to this -- this ratio --

Page 53

1 fluorescence ratio. You can't do it without more
2 information, and that is the essence of our argument
3 across the board.

4 This alone cannot be sufficient, that, in
5 fact, you called it a method in the patent, if you look
6 at the '591 again, Columns 18 and 19, you will see
7 specifically they called it their method, and then they
8 give you their recipe. Without the recipe, nobody can
9 figure this out unless you make the assumption that, oh,
10 it's obvious. Well, if it was obvious, why would you
11 have to know the exact amount of magnesium, the exact
12 temperature, and the exact cycle base in order to -- in
13 order to determine what the appropriate level of
14 fluorescence is?

15 It's the same argument for all of them, Your
16 Honor. If we're right and you have to have a recipe,
17 then we're correct, and it's -- it then becomes
18 means-plus-function. If it's not a recipe, then it's
19 indefinite because you cannot figure out how in the
20 world to do this.

21 If you remember -- if we go back to the
22 earlier slide where we had the recipe up, and let's go
23 to the next slide here, here is Column 19, No. 5, it is
24 headed, and this is in every one of the patents. This
25 is the same recipe. Method for monitoring PCR

Page 54

1 amplifications using oligonucleotide probe. This is the
2 method they disclosed, and you have to know what the
3 magnesium concentration is. Instead of making it four,
4 if you made it eight, what happens? If you make it 80
5 cycles, what happens? If you change the degree, you
6 change the result.

7 I don't know how you can do it otherwise.
8 It's a bit like saying, I can make you an apple pie
9 without giving you any information about how to do it
10 and assume that, oh, well, you know, you know what
11 apples are, you'll figure it out. That is, in essence,
12 what they're saying.

13 That cannot be right, and if it was right,
14 you wouldn't need to have this much detail covering all
15 of their critical parameters in order to get to this
16 hope for greater than six. That's all -- all I have,
17 Your Honor.

18 THE COURT: Okay. Thank you.
19 Any rebuttal?

20 MR. MALONEY: We do, Your Honor.

21 THE COURT: Just -- before you get up there,
22 I don't allow sur-rebuttal, so take your shots now.
23 Don't be holding back.

24 MR. JOHNSON: I understand, Your Honor.

25 THE COURT: All right.

Page 55

1 MR. JOHNSON: I didn't think you would give
2 me another shot, but I'll take it if you let me have it.

3 THE COURT: I just historically have not
4 allowed sur-rebuttals.

5 MR. JOHNSON: That's all right.

6 MR. MALONEY: If we could have just a
7 small -- small break.

8 THE COURT: Why don't we take 10 minutes
9 We'll come back and hear the rest of the arguments.
10 Back in 15 is fine.

11 MR. MALONEY: Okay.

12 MR. JOHNSON: All right.

13 LAW CLERK: All rise.

14 (Recess.)

15 LAW CLERK: All rise.

16 THE COURT: Please be seated.

17 All right. Rebuttal?

18 MS. SCHMID: Thank you, Your Honor.

19 Your Honor, I'll walk through each of the
20 terms in the same order we discussed them before. I'll
21 begin with the term quencher molecule.

22 If I could have Slide 6.

23 Defendant's argument regarding quencher
24 molecule relies on part of the prosecution history that
25 discusses substantially quenched. But they're confusing

Page 56

1 the idea of quenching with the idea of emission. So you
2 may remember, this is a quencher molecule. This is a
3 fluorescent quencher molecule on top. It does two
4 things. One is it absorbs the fluorescence from the
5 reporter. That's the process that's called quenching.
6 The second thing it can do but doesn't have to do is
7 emit light. We know this because a dark quencher
8 absorbs light from the reporter. It's still a quencher.
9 It's still quenching the reporter, quenching the signal
10 that comes from the reporter.

11 So when the patentees were discussing with
12 the Patent Office whether or not these quencher
13 molecules substantially quench, what they're talking
14 about is this red line. Does all of that red line go to
15 the blue line? However what we're debating in
16 construction is this blue line. Are both of these
17 quenchers are only the ones that are fluorescent
18 quencher (sic).

19 But as Defendants themselves define, this
20 dark quencher is still a quencher, and as we discussed
21 earlier, the intrinsic record is very clear. The -- the
22 patentees know how to claim a fluorescent quencher when
23 they want to, but they don't always claim it. Sometimes
24 they just claim a quencher molecule.

25 They in the specification multiple times say

Page 57

1 fluorescence -- quenchers can be fluorescent or they can
2 be nonfluorescent. The fact that some of the claims use
3 a ratio that has the emission of the quencher on the
4 bottom, yes, it means that those particular claims
5 cannot include a quencher where the emission is 0.

6 It is worth noting that even some quenchers
7 that are called dark quenchers, the emission may just be
8 very, very low and may not actually be 0. So those
9 kinds of quenchers just because dark was in their name
10 would not be excluded from those claims. But
11 regardless, there's a variety of ratio claims in the
12 patent. Some of them involve quencher fluorescence, but
13 many of them don't. Some of them are just talking about
14 reporter -- reporter fluorescence.

15 The patentees knew how to use the words they
16 wanted to use, they used the words they wanted to do,
17 and ultimately, if the Court disagrees, perhaps some of
18 the claims are invalid, but given how clear the
19 intrinsic record is, the Court should not try to save
20 the patentees from themselves and try to, in order to
21 preserve the validity of certain claims, ignore what the
22 entire intrinsic record has said about quencher
23 molecule.

24 THE COURT: Well, what claims would not be
25 at risk?

Page 58

1 MS. SCHMID: The majority of them.
2 Essentially, it is one claim that has this term at
3 issue. I believe it is Claim 24 of the '848 patent.

4 In later patents --

5 THE COURT: I'm sorry, tell me that again.

6 MS. SCHMID: Claim 24 of the '848 patent
7 includes the ratio.

8 While there are other claims in later
9 patents that discuss a ratio, each of those requires a
10 fluorescent quencher.

11 THE COURT: Okay.

12 MS. SCHMID: This is the only one that has
13 the quencher on the bottom.

14 THE COURT: Your validity argument is that
15 it wouldn't -- those claims that require comparisons
16 would not be at risk because they don't require a ratio
17 as -- as the comparison?

18 MS. SCHMID: The only -- the only claims
19 that would be at risk, if -- if there is this dark
20 quencher, would be a claim that specifically has
21 emission of the quencher on the bottom of a -- of a
22 ratio, and that's pretty much the only one that
23 doesn't --

24 THE COURT: Right. Okay.

25 MS. SCHMID: -- limit it to a fluorescent

Page 59

1 quencher.

2 Bottom line, the reason that Defendants are
3 arguing this, they are very -- while they say this is
4 about preserving validity, they haven't raised that
5 point with any of the other claims. What this is really
6 about, it's them trying to get some of their infringing
7 products off the hook.

8 Their main -- one of the main quenchers they
9 use is called BHQ, which stands for black hole quencher,
10 so what they want to do is say, hey, by the fact that
11 we're using BHQ, we want to get off the hook for
12 infringing your claims.

13 So as much as Defendants are purporting to
14 care about the validity of -- of Plaintiffs' -- of
15 Plaintiffs' patents, really what this is about is
16 non-infringement.

17 The next term is hairpin structure. Now,
18 I'm going to switch to the ELMO, I believe. And
19 Defendants here showed some discussion with the Patent
20 Office from Exhibit G. I'm going to try and put the
21 same thing up. And as part of this, this is the part of
22 the prosecution history -- I'm on Exhibit G. What the
23 applicant said is the intention of applicants to exclude
24 probes which are designed to form hairpin structures.

25 Defendants argue that what applicants are

Page 60

1 doing here is saying that hairpin structures cannot be
2 probes as we defined hairpin structures, but that's
3 misreading the context of what's going on here.
4 Remember, when we looked at the claim earlier, we saw
5 that hairpin structure is a negative limitation. The
6 patentees are saying, we're claiming probes unless they
7 form a hairpin structure. And the reason is a
8 particular kind of prior art called molecular --
9 molecular beacons.

10 Now, as the Court may have determined from
11 the briefing, what these patents are about is a certain
12 kind of probe and about the relationship of the reporter
13 and quencher. Prior to these patents, there was a
14 structure called the molecular beacon structure which
15 used a hairpin structure to bring a reporter and a
16 quencher next to each other, but this patent was the
17 first time that people found a way to have probes that
18 had the reporter and quencher together without that
19 hairpin structure, which is why in the claims there's
20 the negative limitations saying, our probes are probes
21 that do not form this hairpin structure, which is
22 exactly what they're explaining to the examiner here.

23 The intention of applicants is to exclude
24 those probes that are designed to form a hairpin
25 structure. So far from saying that hairpins cannot be

Page 61

1 probes, what this is saying is the type of hairpins
2 we're talking about here are probes. They're the probes
3 which form hairpin structures. That's exactly what the
4 examiner and the patentees are talking about, which is
5 why the Defendant's construction, which ignores the
6 reporter and quencher, cannot be right. The intrinsic
7 evidence is full of examples that what hairpin
8 structures are talking about is bringing the reporter
9 and quencher together.

10 Defendants argue that a hairpin must have at
11 least three basepairs in the stem, and they show some
12 examples from -- from the intrinsic record. We don't
13 disagree that that's part of the plain and ordinary
14 meaning of hairpin, and certainly if the Court believes
15 that that would provide further clarification for a
16 jury, just as we're asking the Court to provide
17 clarification about the meaning of proximity, we would
18 not be opposed to including in addition to the
19 relationship of the reporter and quencher that the stem
20 must include at least three basepairs.

21 But what the intrinsic record is extremely
22 clear about is that a hairpin structure is not
23 necessarily just a general hairpin structure of any
24 sequence of DNA. It's about a probe that's folding back
25 on itself to bring a reporter and quencher together.

Page 62

1 The next term is the term relating to
2 separation of reporter and quencher molecules.
3 Defendant's only argument is the plain and ordinary
4 meaning. Given that there's a definition in the
5 specification which is applied in the prosecution
6 history, this is the definition the Court should adopt.

7 On terminal nucleotide, still, the
8 Defendants are using the word of the term in their
9 proposed construction. Plaintiffs believe no
10 construction is -- is needed. If, in fact, the Court
11 decides a construction is needed, Plaintiffs provided
12 the plain and ordinary meaning based on the intrinsic
13 record.

14 Turning to the monitoring the fluorescence,
15 now, an analogy that Plaintiffs (sic) used relating to
16 the later terms, the factor of six, that applies
17 throughout is this idea of the apple pie, that you need
18 very specific instructions to be able to make an apple
19 pie.

20 MR. JOHNSON: That was my analogy.

21 MS. SCHMID: I'm sorry.

22 MR. JOHNSON: You said, Plaintiffs.

23 MS. SCHMID: I said, Plaintiffs. I'm so
24 sorry, the Defendants.

25 Now, while this may be very true for someone

Page 63

1 like me who's not good at baking, I certainly need
2 pretty specific instructions. For one of skill in the
3 art of cooking, you can certainly go to a chef and say,
4 I'd like an apple pie, and they know how to make an
5 apple pie. You can say, I'd like an apple pie with a
6 lattice crust, and they can make that kind of apple pie.

7 And that's what monitoring the fluorescence
8 is like. Defendants have argued that people didn't know
9 how to monitor fluorescence, but this is pure attorney
10 argument. They've submitted no expert declaration.
11 Quite to the contrary, the -- the two references that
12 Plaintiffs described, the Higuchi references, both
13 clearly described in a scientific journal exact steps
14 that they took to monitor fluorescence. One of skill in
15 the art could read those papers and apply the techniques
16 taught in those two papers.

17 Finally, the last three terms relating to
18 optimization. Again, while Defendants are arguing that
19 one of skill in the art would have needed an exact
20 recipe, they're offering only attorney argument for this
21 proposition.

22 However, Defendants -- Plaintiffs have
23 offered evidence that, in fact, skilled artisans knew
24 how to optimize conditions.

25 If we go to Slide 65.

Page 64

1 Plaintiffs have cited two pieces of art
2 showing PCR buffer optimization, different
3 optimizations. Skilled artisans knew what PCR reactions
4 were. They were invented long before these patents were
5 filed, knew how -- what the different factors were that
6 impacted them. Knew how to do tests to figure out which
7 conditions worked for which reactions. To the extent my
8 answer to the Court's question was confusing before, I
9 would like to clarify.

10 THE COURT: It's probably a product of the
11 Court's question being confusing as opposed to your
12 answer.

13 MS. SCHMID: My answer may have been
14 confusing, so to make sure we're on the same page, what
15 I intended to say was the test for this, it's simple. A
16 skilled artisan would optimize a PCR reaction as they
17 knew how to do very, very well, and at that point,
18 fluorescence readings would be taken, and it's a yes or
19 no question. Does it meet this ratio?

20 So going back and trying to tinker with the
21 ratio saying, oh, I didn't like that result, let me try
22 again, and going outside of that optimized range, that
23 would not infringe the patent.

24 THE COURT: Has the method of optimization
25 in the art changed from 1994 until today?

Page 65

1 MS. SCHMID: I'm not sure, but it certainly
2 could be at the time these patents were filed is the
3 optimization that would apply.

4 THE COURT: And that's -- I mean, that's
5 kind of what I was driving at, although inartfully, is
6 unless we know under which conditions the measurements
7 are to be taken, how does one know whether the
8 comparison or the -- the products that are yielded by
9 the tests are those that are involved in the claims so
10 that we can determine infringement or non-infringement?

11 MS. SCHMID: Yes. The optimization as it
12 would have been applied at the time of filing is the
13 optimization that would apply.

14 THE COURT: Okay. I mean, I agree with
15 that proposition, I just didn't know if we needed to
16 make it clear so that there's -- there's not any debate
17 on down the road as to which optimization is the
18 accurate.

19 MS. SCHMID: And if there are no further
20 questions from the Court, the Plaintiffs thank the Court
21 for his time.

22 THE COURT: I'm not going to try that again.

23 MS. SCHMID: Oh, I guess in summary -- oh,
24 no, actually, two -- I'm so sorry. I have two slides.

25 One of which is Defendants also reiterated

Page 67

1 this -- this word about, and what kinds of prior art
2 were the patentees and the examiners talking about?

3 So in conclusion, Your Honor has heard two
4 different approaches to claim construction today. The
5 Plaintiffs described using definitions of claim terms in
6 the specification where they're provided, using the
7 plain and ordinary meaning of words, and applying
8 controlling law. For example, looking at the law on
9 means-plus-function and likewise looking at the law on
10 applying definitions from Phillips.

11 And, similarly, the Courts cannot rewrite
12 claims to preserve their validity. Defendants, on the
13 other hand, are ignoring definitions from the
14 specification, they're ignoring plain and ordinary
15 meanings, and instead they're setting up complex
16 self-serving rules to set up some undisclosed invalidity
17 or non-infringement arguments.

18 For these reasons, the Plaintiffs ask the
19 Court to adopt its constructions.

20 Thank you, Your Honor.

21 THE COURT: All right. Thank you.

22 I'll get you an order out. It will be -- I
23 think I can get one out to you fairly quickly. Are
24 there any other matters that we need to take up, case
25 management, while I've got you here? Anything that

Page 66

1 several times that the conditions have to come from the
2 single example in the patent.

3 Switching back to the ELMO.

4 THE COURT: The dark quencher.

5 MS. SCHMID: It is. Does anyone know how I
6 turn it to a light quencher?

7 Okay. So Phillips already considered that
8 argument and rejected it stating, we have expressly
9 rejected the contention that if a patent describes only
10 a single embodiment, the claims of the patent must be
11 construed as being limited to that embodiment. Instead
12 the test is what one of ordinary skill in the art would
13 have understood at the time.

14 In summary -- one other quick point before I
15 summarize. Just to reemphasize on the term hairpin
16 structure, as discussed, there is an express definition
17 given in the record, and as we explained throughout the
18 intrinsic record, there's an emphasis that what the
19 patentees are really talking about is bringing the
20 reporter and quencher together.

21 This Court expressed some skepticism about
22 the clarification of proximity as "next to." The word
23 "together" expresses that just as well, and it's the
24 same word that the patent examiner used, but really got
25 at the idea of why is this limitation in there, what is

Page 68

1 y'all know --

2 MR. JOHNSON: None, Your Honor.

3 MR. MALONEY: None from our perspective,
4 Your Honor.

5 THE COURT: Okay. I just -- since I had
6 y'all here, I'd rather, if there's any problems, try to
7 deal with them today as opposed to --

8 MS. SCHMID: One order, the parties have
9 been discussing a possible modification to the
10 scheduling order. Currently expert reports are due 30
11 days after the issue of claim construction ruling, and
12 the parties are discussing stipulating to a later date
13 since discovery doesn't close until early summer.
14 However, the parties have not yet agreed on a specific
15 date, so that will be submitted later.

16 THE COURT: If you can agree to a date,
17 submit an agreed order and I'll sign it.

18 MS. SCHMID: Thank you, Your Honor.

19 THE COURT: If there's a dispute about it,
20 you know, file a motion and I'll probably try to deal
21 with it on the papers as opposed to having any kind of
22 hearing. If I do a hearing, I'd probably do it
23 telephonically just so that I can -- if there is
24 anything that wasn't fully vetted in the papers. I
25 would suspect that would be the type of thing y'all can

Page 69

1 resolve by agreement, okay?

2 MR. JOHNSON: Thank you, Your Honor.

3 THE COURT: Thank y'all.

4 LAW CLERK: All rise.

5 THE COURT: Y'all travel safely.

6 MR. JOHNSON: All right.

7 MR. HAWES: Thank you, Your Honor.

8 (Recess.)

Page 70

1 CERTIFICATION

2
3 I HEREBY CERTIFY that the foregoing is a
4 true and correct transcript from the stenographic notes
5 of the proceedings in the above-entitled matter to the
6 best of my ability.

7
8
9 SHELLY HOLMES

Date

10 Deputy Official Reporter

11 State of Texas No.: 7804

12 Expiration Date: 12/31/12